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(71) Applicant: **Shepperd, John Anthony Norman**
Hemingfold Telham
Near Battle East Sussex(GB)

(72) Inventor: **Shepperd, John Anthony Norman**
Hemingfold Telham
Near Battle East Sussex(GB)

(74) Representative: **Baillie, Iain Cameron et al**
c/o Ladas & Parry Isartorplatz 5
D-8000 München 2(DE)

(54) Spinal implant.

(57) A spinal implant has an elongate body (1) which is divided into two portions (5, 6) with mutually opposed contact surfaces (5A, 6A) and is for insertion into the joint space between two adjacent vertebrae. A cam device (3) or cam devices are movable between the contact surfaces to expand or increase the spacing between the body portions so as to increase the spacing between the adjacent vertebrae.

The implant has a porous external surface to facilitate bore and cartilage tissue growth therein. Alternatively, the external surface is smooth and coated with a bioactive material such as a hydroxyapatite, for example, tricalcium phosphate. In both instances bone, cartilage tissue and external surfaces of the implant are fused together to prevent migration of the implant. Advantageously, insertion of the implant requires a minimum incision in skin and cartilage tissue.

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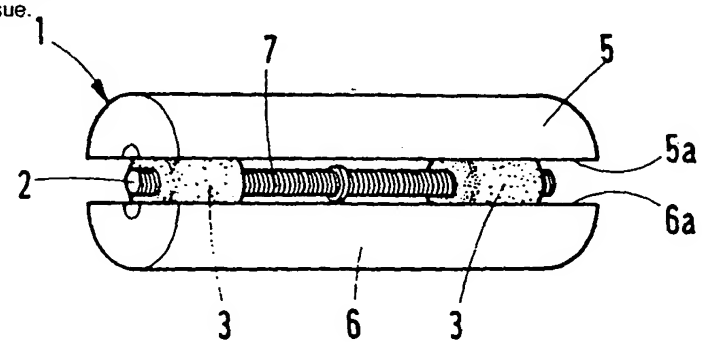


Fig.2

SPINAL IMPLANT

This invention relates to spinal implants.

The spine is a flexible structure of about two feet in length comprising thirty-three vertebrae, twenty-eight of which are separate bones and five of which are fused to form the sacrum. A typical vertebrae consists of bony mass in front, that is the side of the spine closest to the skin, called the body and an arch behind which together form a ring through which the spinal cord passes. Three processes extend from this ring, one at either side called the tansverse processes, and one at the back which is known as the spinous process. These give attachment to the muscles which support and move the vertical column.

The vertebrae move on each other by means of their articular processes, whilst the bodies are separated from each other by thick circular pads of fibro-cartilage, called the inter-vertebral discs, which give the whole structure subtleness and deaden jars. Strong ligaments bind the vertebrae together.

Where, by disease or injury, the spine has an unnatural curve, referred to as a scoliosis, it is possible to achieve spinal fusion with the spine in its correct position by using spinal implants. Spinal fusion has been employed for stabilising segments of the spine for a number of decades and various surgical approaches to the problem are known, including anteria approach and interbody fusion, posterial interspinous fusion, postero-lateral fusion and inter-transverse fusion. In all cases either autograft, homograftd or heterograft bone is employed and for some methods an implant is used to achieve immediate fixation.

Interbody fusion with distraction, that is stetching of the spine into a natural position, has been a desirable goal because in distracting vertical end plates, nerve root canal size is increased and thus the risk of nerve root pressure and nerve root irritation is eliminated or reduced. Unfortunately, distracting the vertebral end plates can only be retained by bone graft which in most instances collapses.

One particular type of spinal implant comprises an elongate rod having an attachment device mounted on each of its two ends, the attachment device serving for connection with the spinal column. The rod is rotatable relative to both attachment devices and one of the devices is screw-threadingly attached to the rod so that upon rotation of the rod the attachment device moves longitudinally there to achiev stretching of the spinal column. The rod may have mounted upon it a backing sleeve which is movable along the rod until centered over a superior facet of a fractured or most posteriorly displaced vertebrae. With the sleeves in place moderate distraction can be applied in stages. With correct positioning and selection of sleeve size the injured segments are held in a clinically rigid condition anatomically aligned in all planes. The disadvantage with such arrangements is that they are permanently rigid and have contact with the bone over a relatively small area.

It is desirable therefore to provide a permanent implant to substitute a full bone graft in establishing distraction into body fusion.

According to the present invention there is provided a spinal implant comprising an elongate body divided longitudinally into two portions and being insertable in the joint space between two adjacent vertebrae, engageable contact surfaces between the body portions, and expansion means movable between the contact surfaces of the body portions for spacing body portions apart and adjusting the joint spacing between adjacent vertebrae.

The spinal implant is preferably cylindrical and divided longitudinally into two halves. The body may be divided into more than two portions, preferably four portions. The expansion means is located between the two body portions and preferably comprises an elongate rod having an outer screw thread on at least part of its outer surface and cam means mounted on the screw threaded part. The cam means is of a greater diameter than the internal diameter of the body and sits within an enlarged cavity defined between the body portions.

When the rod is rotated the cam means move along the rod and forces the two body portions apart as the cam means engages the side walls of the enlarged cavity within the body. The more the rod is turned the further the cam means moves thus increasing the spacing between the body portions.

Preferably the cam means comprises two sleeves each locatable within its own enlarged cavity within the body and being screw-threadedly mounted on the rod. Rotation of the rod in one direction moves the cam means outwardly towards the ends of the body, whilst rotation in the opposite direction moves the cam means towards each other until the cam means meet centrally of the body. In this latter case the body will rock at its extreme ends thus ensuring subtleness between injured or diseased vertebrae.

In a further embodiment of the present invention the implant body has abutting flat contact surfaces which are each provided with a single concave recess which receives the convex surfaces of a cam d vice which is pushed between

the housing or body portions. The body portions each have a threaded bore for receiving the threaded ends of support rods or wires therein and the cam devic has elongate grooves therein for freely supporting the wires whilst the cam device is presented to the body portions in the non-distracted condition of the body portions. Conveniently, in the distracted condition of the body portions, with the cam device located therebetween, the wires are displaced from the grooves in diametrically opposed directions.

Preferably the outer surface of both implants is a porous titanium material for permitting and encouraging bony ingrowth and complete anchorage of the implant within the bone of the vertebrae.

Embodiments of this invention will now be described by way of example with reference to the accompanying drawings in which:

Fig. 1 is an external perspective view of a first embodiment of a spinal implant according to the present invention,

Fig. 2 is a perspective view of the implant of Fig. 1 with the portions of the body of the implant in a spaced apart condition,

Fig. 3 is a cross-sectional view of the spinal implant in a closed position,

Fig. 4 is a cross-sectional view of the spinal implant of Fig. 3 in an expanded and locked position,

Fig. 5 is a view similar to that shown in Fig. 4 but with the implant in an expanded rocking condition,

Fig. 6 is a part sectional side elevational view of a second embodiment of a spinal implant according to the present invention and part of an insertion instrument,

Fig. 7 is a cross-sectional view along the line A-A of Fig. 6,

Fig. 8 is a view similar to that in Fig. 6 with the spinal implant in an expanded condition, and

Fig. 9 is an end view from the left hand end of Fig. 8.

Referring in detail to Figures 1 through 5, one spinal implant comprises an elongate cylindrical body 1, an elongate rod 2 extending along the longitudinal axis of the body 1, and two cam devices 3 mounted on the rod 2.

In the closed position illustrated in Fig. 1 the elongate body 1 is cylindrical with a central elongate circular aperture 4 extending the whole length of the body for receiving the rod 2. The body itself is divided into two equal portions 5, 6 which simply abut each other along flat contact surfaces 5A and 6A, and include an elongate recess on each portion thereby defining the aperture 4 therebetween.

The elongate rod 2 has an ext rnal screw thread 7 along the whole of its length which mates with an internal screw thread of an elongate c ntral aperture through the cam devices 3. Screw thread 7 is divided into two oppositely pitched threads, one left-handed and the other right-handed so that upon rotation of the rod 2 in one direction the cam devices 3 move in opposite directions either away from each other or towards each other in dependence upon the direction of rotation of the rod 2.

The aperture 4 extending along the body has, at least over part of its length, an internal diameter which is substantially identical to the external diameter of the rod 2. Along the length of the aperture 4 there are provided two recesses of enlarged diameter which are each of a general size to receive a respective cam device 3 when the body is in its closed position shown in Fig. 1. The end surfaces of the cam devices 3 are sufficiently curved so that when they abut the ends of the recess 8, 9, th sleeve is forced to pass from the recess and gradually separates the body portions until the cam devices are fully located between the body portions 5 and 6 as shown in Figs. 4 and 5. The rod 2 can be provided at its end with either an Allen key drive or a diametrical slot for receiving the head of a screw driver. The rod 2 may be adapted to be rotated by any other suitable means.

The cam devices 3 are preferably nylon sleeves having an internal screw thread with the same pitch as the respective threaded portion of the rod 7.

In use the spinal implant is located between two vertebrae to replace the intervertebral disc therebetween and for this purpose the outer surface of the implant is of porous titanium to obtain sufficient bone ingrowth and thereby provide a sound interference fit with the adjacent vertebrae. Should any disadvantage arise with titanium, other materials such as chrome cobalt, stainless steel or ceramics could be used.

With the spinal implant in position the threaded rod 2 is turned clockwise using an Allen key, for example, in a suitable recess in one end of the rod 2. As the rod rotates in a clockwise direction the cam devices 3 travel towards the opposite ends of the body and as they do so they create a wedge between the body portions and subsequently a graduated expansion of the device to the expanded position shown in Fig. 4. By turning the rod in an anti-clockwise direction the cam devices 3 travel towards the centre of the device creating a similar expansion of the implant to that shown in Fig. 4. However, the Fig. 4 condition has the effect of providing a firm immovable implant whilst in the condition shown in Fig. 5 the extreme opposite ends of th body are rockable on the cam devices so that the body portions 5, 6 at the respective

ends thereof are movable towards or away from each other. In this latter condition the required spacing between vertebrae is maintained but spinal movements are also maintained and thereby the spinal implant acts as a replacement of the normal intervertebral disc.

Figures 6 to 9 show a second embodiment of a spinal implant according to the present invention together with part of the barrel of a "pistol" like instrument used to locate a cam device between split body portions of the spinal implant.

The spinal implant specifically shown in Figures 6 to 9 comprises an elongate cylindrical body 20 rounded at one end 21 and divided into two substantially identical portions 22, 23. The portions 22, 23 in the closed position of the spinal implant have abutting flat surface portions 24, 25 at the opposite ends of the implant and a centrally located shallow recess 26 defined between the two portions 22, 23.

At the left hand end of the spinal implant 20, as shown in Figures 6 and 8, there is provided in each portion 22, 23 an elongate threaded bore 27, 28 respectively which are arranged to receive support rods or wires 29, 30 screw-threadingly engaged with bores 27, 28. As shown in Figure 8 the body portions 22, 23 of spinal implant 20 are curved adjacent flat portions 25 to facilitate spacing of the body portions 22, 23 when a cam device 31 is to be located therebetween.

The cam device 31 is of a one piece construction and a generally rectangular cross-section having flat upper and lower surfaces 32, 33 at opposite ends of cam device and a central outwardly curved surface portion 34 for location within the curved recess portions of the body defining the recess 26. As more clearly seen in Figures 7 and 9, the cam device 31 has elongate grooves 35, 36 on opposite sides thereof extending the whole length of the cam device 31. The grooves 35, 36 receive the wires 29, 30 respectively, which wires act to guide the cam device 31 to engage the sloping surfaces at the left hand end of the spinal implant as shown in Figures 6 and 8. As the cam device is forced between the body portions 22, 23 of the spinal implant 20 the wires 29, 30 move in dimetrically opposite directions to allow the cam device to be located between the parts of the spinal implant. A left hand end view of the spinal implant in Figure 8 is shown in Figure 9 where the wires are shown to be completely disengaged from the grooves 35, 36.

The spinal implant shown in Figures 6 to 9 is of the fixed type where the cam devic once located between the body parts of the spinal implant fix the body portions 22, 23 relative to each other because of the contact between the flat surfaces 32, 33 and the flat surface portions 24, 25 of the body portions. However, to achieve a spinal implant in which the body portions can rock one relative to the other a cam device is provided which has outwardly curved portions 34 but does not have the flattened surface portions 32, 33 so that the curved portions 34 define a rocking surface for the curved recessed parts of the body portions defining the recess 26.

This second embodiment of the spinal implant according to the present invention also has an outer surface which is of porous titanium to obtain sufficient bone ingrowth and provide a sound interference fit with the adjacent vertebrae. Chrome cobalt, stainless steel or ceramics can also be used. Whilst the cam device is slidable in the longitudinal direction of the spinal implant 20 to achieve a slight amount of movement in the transverse direction between the two body portions the spacing between the two body portions is mainly controlled by preselecting the thicknesses of the cam device.

Preferably, the outside diameter of the wires 29, 30 are 1.7 mm (10 p.a) and the maximum separation achieved by the wires, as shown in Figure 9, is less than 10 mm.

The implant instrument has an elongate barrel part of which is shown in Figs. 6 and 8. The barrel of the "pistol" instrument is of a circular configuration as shown in Figures 6 and 7 and has an internal diameter which is sufficiently large to support the cam device 31 which engages the internal surface of the barrel along each of four corners thereof whilst pressure is applied to the cam device to force it between the body portions 22, 23 of the spinal implant.

In use, the body portions 22, 23 are positioned in the inter-vertebral and the cam device is interposed between the body portions to push them apart. The concave surfaces of the recess 26 locate with the convex surfaces of the cam device. To enable rocking between the body portions and the cam device the convex surfaces of the cam device must be opposite one another. In some cases no rock is required and in this situation the cam device is provided with flat parallel surfaces at each end of the convex surfaces.

The body portions are initially suspended on wires outside the barrel of the implant instrument and are introduced into the joint space between adjacent vertebrae. The threaded support wires 29, 30 which are mounted on the pistol unit and extend from the barrel of the "pistol" are dis-engaged from the threaded bores of the body portions. The cam device which is initially located in the barrel of the pistol is pushed out of the barrel of the insertion

device between the two halves of the spinal implant to separate them. Once the cam device is in position the wires are unscrewed from the body portions and the "pistol" instrument is withdrawn.

Th grooves in the cam device allow the supporting wires attached to the body portions to be close together in a non distracted arrangement so that upon distraction the maximum separation is less than 10 mm. This is necessary to avoid a bolt in nerve damaging instrument.

The maximum spacing between the wires is not limited to 10mm since in an alternative construction the wire receiving bore on each body portion is located adjacent the external peripheral edge of the body portions rather than at the central location of Fib. 7. In this alternative construction, even through the body portions are in contact with one another, the cam device is arranged to pass between the wires. Therefore, the grooves 35, 36 Fig. 7 are omitted from the cam device. In this case the rear end of the cam device, relative to the direction of movement from the pistol device when implanting the spinal implant, is provided with a threaded control bore in which is engaged a wire for applying pressure to the cam device during insertion thereof between the body portions of the spinal implant.

There has been described a various embodiments of a spinal implant in which the basic invention remains the same, that is, that a split body is pushed apart by an interposed cam device to recreate joint space. However, in the latterly described embodiment the interposed cam device is pushed into place rather than moved along a screw threaded device.

Therefore, there has been described spinal implants which can be permanently inserted between vertebrae and can be used in place of bone grafting methods in establishing distraction into body fusion. The spinal implants function both in the surface of the implant being made of a porous titanium material which has the property of permitting and encouraging bone ingrowth and thereby complete anchorage and also in that the implants are split longitudinally and contain an expansion device within its body. By moving the expansion devices vertebral end plates are separated and root canal size re-established. Furthermore, the implants are firmly fixed by a strong interference fit which will achieve immediate rigidity of the appropriate segment of the spine. Preferably, the implant is three centimeters in length by one centimeter in diameter. However, the implant can be of any oth r suitable size and can have a rectangular cross-section.

The spinal implants described herein are of an elongate cylindrical structure so that insertion of the implant betwen spinal vertebrae requires a minimum incision in both skin and cartilage tissue. The cylindrical implant can be provided with external flat surfaces which are for example parallel to the contact surfaces of each body portion to assist in preventing migration of the implant. In one alternative construction the body portions may be of an elongate rectangular shape to provide added stability to the implant although a slightly increased length of incision will be necessary.

As described the spinal implants may be coated in a porous material to facilitate bone and cartilage tissue growth into the surface of the implant. Alternatively the implant may have a smooth nonporous finish which is coated with a bioactive material such as a hydroxyapatite, for example, tricalcium phosphate, which reacts chemically with bone and cartilage tissue to provide bone or tissue attachment to the implant.

Whilst the above embodiments have been described as being divided into two portions the implant bodies can be divided into four portions to allow for expansion of the overall diameter of th spinal implants rather than expansion in just one plane.

The external shape of the cam device may be of different shapes to those disclosed herein and as particularly shown in the drawings, to improve the amount of rocking movement within the implant and hence increase the flexibility between adjacent vertebrae.

One alternative cam device has identical opposed external surfaces each of which has a continuous arcuate curve in the direction of its longitudinal axis from the front to the rear thereof. In a transverse direction to the longitudinal axis the opposed surfaces are straight at the extreme front and rear edges whilst gradually increasing in curvature towards the longitudinal centre of the cam device where also there is a central region where the opposed curved surfaces of the cam device almost meet along the edges of the cam devices.

In the cam device described with reference to Figs. 6, 7 the opposed surfaces are arcuate but relatively thick flat side surfaces are provided along the whole length of the cam device. The sid surfaces of the cam devices may be arcuate to more closely accord with the internal diameter of the barrel of the implant instrument, thus providing more support for the cam devices within the barrel.

In another form the cam devic has a shap substantially identical with that shown in Figs. 6 and 8 but has an addition, and extension at both th front and rear ends ther of with the opposed surfaces thereof being flat so that when located between the body portions of the implant the cen-

tral part of the cam device lies in the r cess defined between the body portions whilst the flat front and rear extensions are engaged by the flat surfaces of the body portions in front of and behind the recessed area thereof. Each of the front and rear extensions are conveniently spaced from the central portion of the cam device by transversely extending grooves.

Alternatively, the expansion device in at least the first described embodiment is replaced by a rotatable cam located in a compartment within the body of the implant so thatupon rotation of the cam expansion between parts of the spinal implant is achieved.

The cam device 3 on the screw-threaded rod 2 can be made to extend a spike from the body as the body parts separate to ensure location of the device within the bone.

Claims

1. A spinal implant comprising an elongate body (1) divided longitudinally into two portions (5, 6) and being insertable in the joint space between two adjacent vertebrae, engageable contact surfaces (5A, 6A) between the body portions, and expansion means (3, 7) movable between the contact surfaces of the body portions (5, 6) for spacing the body portions apart and adjusting the joint spacing between adjacent vertebrae.

2. A spinal implant as claimed in claim 1, characterised in that the contact surface of each body portion is recessed to receive the expansion means.

3. A spinal implant as claimed in claim 1 or 2, characterised in that the contact surface of the body portion has two recesses (8, 9) each arranged to receive a cam device (3) defining the expansion means.

4. A spinal implant as claimed in claim 3, characterised in that the two cam devices (3) are mounted on a screw threaded member (7).

5. A spinal implant as claimed in claim 4, characterised in that the screw threaded member (7) has opposite screw threads with one of the cam devices located on a respective one of the screw threads so that upon rotation of the threaded member the cam devices (3) move towards one another or away from one another.

6. A spinal implant as claimed in claim 1 or 2, characterised in that the contact surface of each body portion (22, 23) has a single rec ss (26) for receiving a single cam device (31).

7. A spinal implant as claimed in claim 6, charact rised in that the cam device has front and rear ends with the rear end having a threaded bore (27, 28) therein for receiving support means (29, 30) of an implantation instrument for inserting the implant between adjacent vertebrae.

8. A spinal implant as claimed in claim 7, characterised in that the threaded bore (27, 28) at the rear end of each body portion (22,23) is substantially adjacent the contact surface thereof.

9. A spinal implant as claimed in claims 6, 7 and 8, characterised in that the cam device (31) has longitudinal grooves (35, 36) therein for receiving the implant support means (29, 30) when the cam device is located in the implant instrument prior to insertion into the spinal implant.

10. A spinal implant as claimed in claim 6 or 7, characterised in that the threaded bore (27, 28) at the rear end of each body portion is located towards the external peripheral surface of the body portions along a central line perpendicular to the contact surface.

11. A spinal implant as claimed in claim 10, characterised in that the cam device has no longitudinal grooves and is arranged to pass between the implant support means (29,30).

12. A spinal implant as claimed in claim 1, characterised in that the cam device has a central curved portion and platform portions are attached thereto at front and rear ends of the curved portion, each platform portion having substantially flat upper and lower surfaces for engagement with the contact surfaces.

13. A spinal implant as claimed in claim 1, characterised in that the cam device comprises a rotatable cam housed in a compartment within the implant and is rotatable within the compartment to vary the spacing between the body portions.

14. A spinal implant as claimed in any one of the preceding claims, characterised in that the exterior surface of the implant is of a porous material.

15. A spinal implant as claimed in any one of claims 1 to 13, characterised in that the exterior surface of the implant is smooth and coated with a bioactive material to chemically bond the bore and cartilage tissue of the vertebrae to the implant.

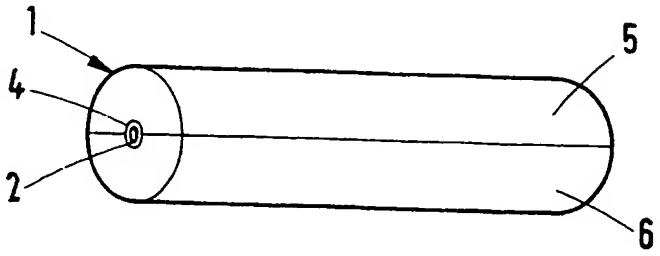


Fig.1

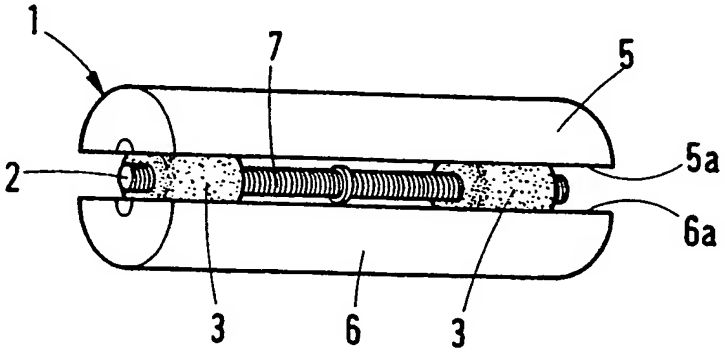


Fig.2

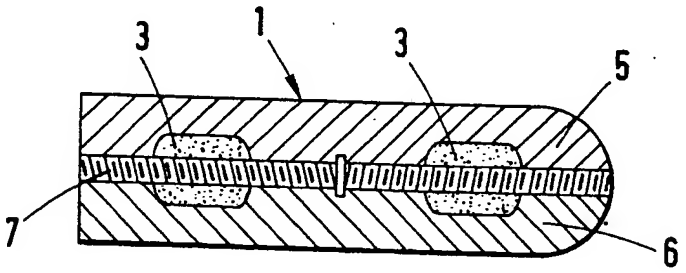


Fig.3

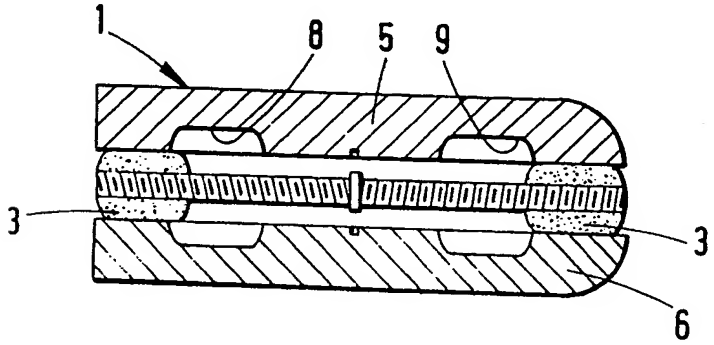


Fig.4

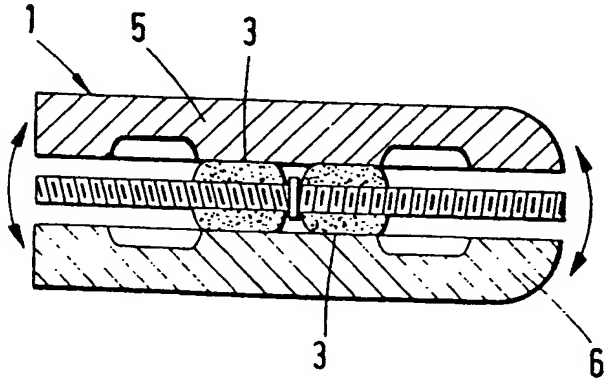


Fig.5

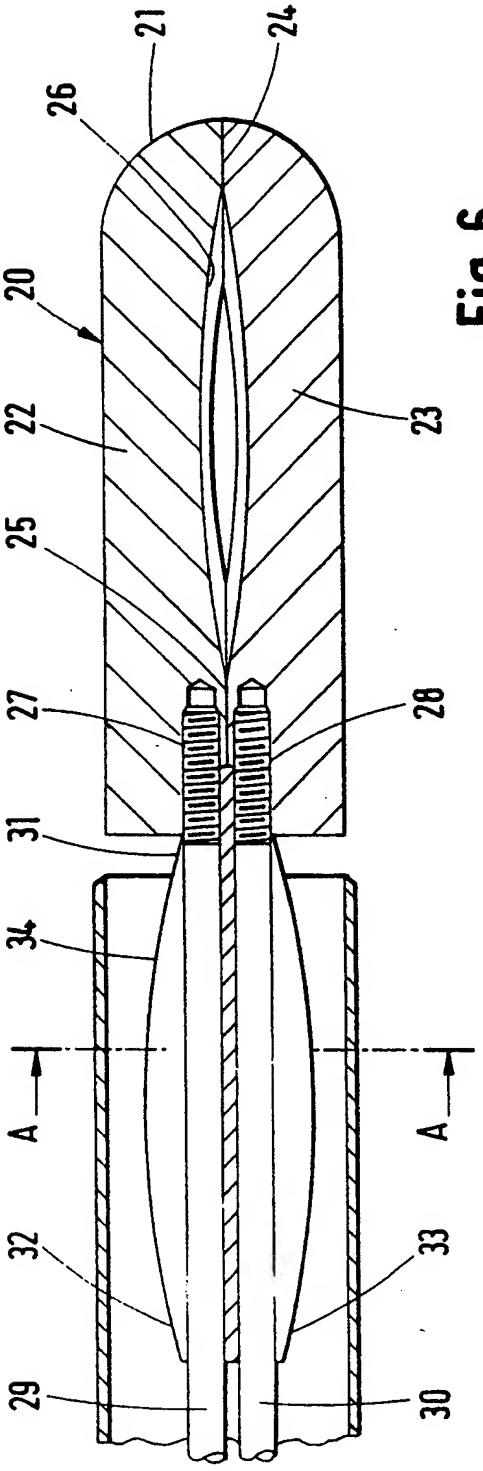
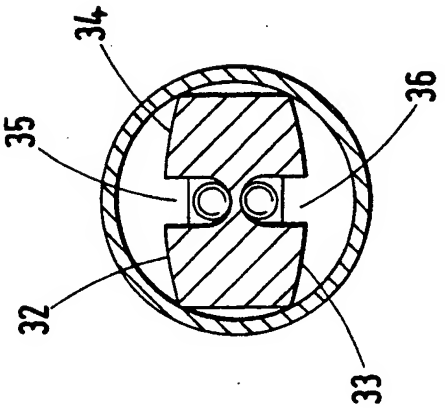


Fig.6

Fig.7



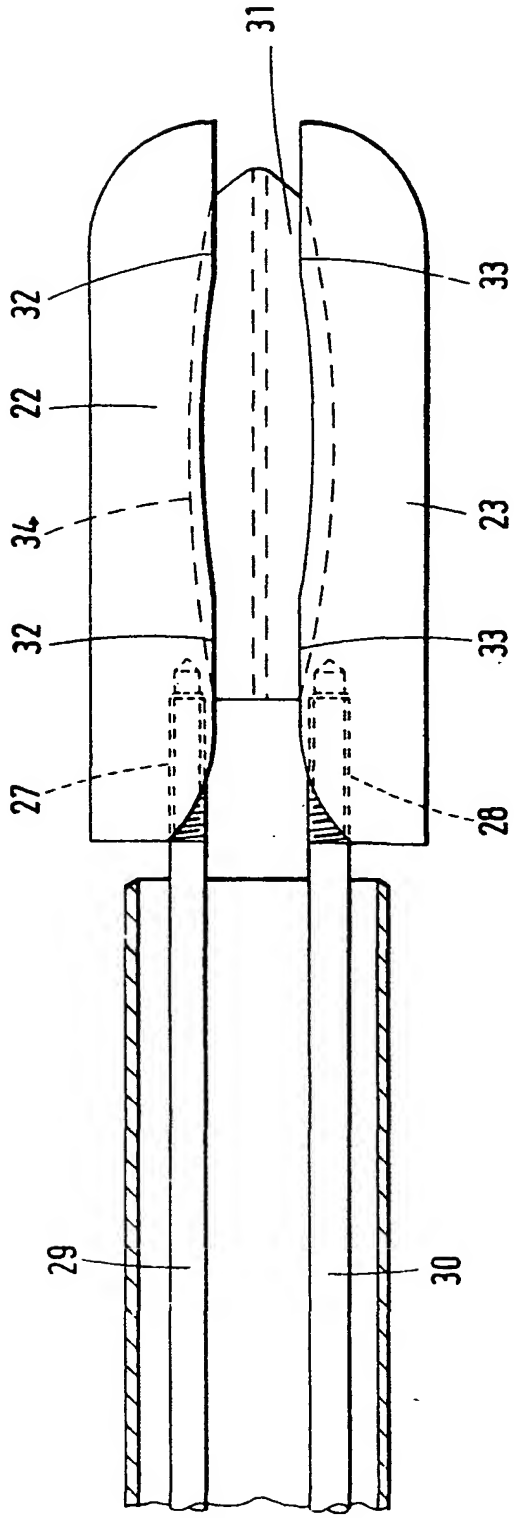


Fig.8

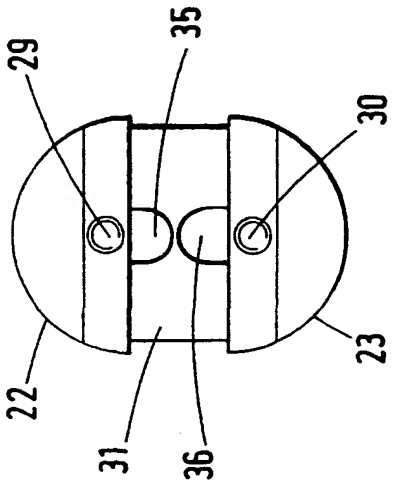


Fig.9

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 87 30 7658

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	US-A-4 401 112 (S. REZAIAN) * Figures 1-4; column 2, lines 1-39 * ---	1	A 61 F 2/44 A 61 B 17/58
A	EP-A-0 077 159 (B. ATKINS) * Figure 5, abstract; page 11, lines 9-23 * ---	1	
A	DE-A-3 023 353 (SULZER AG) * Figures 1,2; claim 1 * -----	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 F
A 61 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	15-12-1987	NEILL M.C.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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D : document cited in the application
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US-A- 4 501 269

(73) Proprietor: **Brantigan, John W.**
328 Overlook Brook Court
Chagrin Falls Ohio 44022(US)

(72) Inventor: **Brantigan, John W.**
328 Overlook Brook Court
Chagrin Falls Ohio 44022(US)

(74) Representative: **McCall, John Douglas et al**
W.P. THOMPSON & CO. Coopers Building
Church Street
Liverpool L1 3AB(GB)

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Description

This invention r lates to the art of prosthetic devices adapted to be inserted transversely in a vertebral column on prepared sites of the opposed faces of adjacent vertebrae forming struts which are fused into the vertebrae to maintain a normal disc space between the vertebrae. These devices are, when inserted in the vertebral column, in the form of rigid inert plugs spanning the disc space in side-by-side relation and having roughened surfaces facilitating ingrowth of bone tissue.

The plugs are mounted endwise on a tool to facilitate insertion between the adjacent vertebrae, have a height that will reclaim the normal disc space and can stretch remaining tissue of a collapsed damaged disc. Preferred plugs have barbs biting into the vertebrae, slots for carrying bone graft material, tapered leading ends facilitating insertion between the vertebrae and are formed from a radiolucent material.

The leading cause of low back pain arises from rupture or degeneration of lumbar intervertebral discs. Pain in the lower extremeties of the back (sciatica) is caused by compression of spinal nerve roots by damaged discs between the vertebrae and low back pain is caused by collapse of the disc and the adverse effects of bearing the majority of the body weight through a damaged unstable vertebral joint. Surgical treatments for relief of the sciatic pain and lower back pain generally include the following:

1.) Excision Of The Ruptured Soft Disc

This procedure removes the portion of the disc compressing the spinal nerve and is generally successful in relieving the sciatic leg pain but in more than half of the cases, there is a recurrence of back pain. Over a period of time the disc gradually loses height due to the rupture and this loss of height causes the posterior facet joints of the vertebrae to fit incorrectly resulting in arthritic change in all elements of the spinal segment. Recurrent nerve root compression due to bony encroachment (spinal stenosis) also develops. The continuing and recurring back pain from this source has created a leading source of pain and disability.

2.) Disc Excision With Posterior Fusion

Traditional posterior fusion, creating bone growth between the bony laminae, or postero-lateral fusion between the transverse processes prevents motion between th adjac nt vertebrae but does not alter th fact that approximately 90% of th body w ight must be transmitted through degenerated discs causing pain. Further, posterior fusion tends to caus bony overgrowth leading to nerv root compression by spinal stenosis.

3.) Disc Excision With Anterior Interbody Fusion

Interbody fusion techniques, in which the soft disc is completely excised and replaced with either the patient's own bone (autologous bone) or with transplant banked bone (homologous bone) are generally successful if solid fusion can be obtained between adjacent vertebrae bodies. Unfortunately, the success rate has only been about 50%.

4.) Disc Excision With Posterior Lumbar Intervertebral Fusion (PLIF)

This procedure reconstructs the normal anatomic relationships between the bony and the neural structures and has many advantages. Weight bearing through a solid bony fusion made between vertebral bodies relieves the mechanical pain of the traditional unstable degenerative disc and generally prevents long term disc collapse or further degenerative changes. The complete disc excision prevents recurrent herniation of the same degenerated disc.

However, this PLIF procedure has several serious disadvantages in that it is technically very difficult, and, therefore, not as successful or widely used as it might be. It entails large amounts of blood loss in a small deep hole causing physiological stress to the patient and psychological distress to the surgeon. Further, the use of autologous bone graft from the patient's own iliac crests extends the operation and creates a second painful operative site. Because it is difficult to obtain a large enough quantity of autogenous bone with sufficient strength, homologous bank bone is generally used.

Interbody bone grafting involves the problems of strength and that of bone incorporation. Strong cortex bone (the outer layer) is required as a strut in the interbody position to prevent collapse of the disc space while healing occurs. The surgeon has the unfortunate requirement of having to fashion the required struts with handheld tools during the operation and these cortex bone struts are not wide enough for optimum load bearing and they anchor themselves by healing process that occurs very slowly over a matter of years. Further, soft cancellous bone, which heals more reliably over a matter of 12 to 18 months, is also required for a traditional interbody fusion.

It is well understood in orthopaedic surgery, that grafted bone heals by a process called "creeping substitution" in which blood capillaries first grow into the grafted bone, th graft d bon is reabsorb d, and th n n w bon c lls are laid down along the bony matrix of th graft. During th tim

that the structural bone graft struts ar being reabsorbed, motion must still be prevented in the involv d segments and although a brace or cast is often used, the entire process has proven less reliable than desired. Homologous back bone, being more "foreign" requires a much longer time to grow together and has a higher failure rate estimated at three times the failure as with the patient's own bone. In effect, neither source of bone is optimum for the fusion procedure.

EP-A- 0042271 discloses an invertebral disc prosthesis comprising a body of biologically-acceptable material suitably dimensioned and shaped to replace a natural disc. In some embodiments a circular threaded hole is provided to secure a threaded end of a holding instrument to facilitate insertion of the prosthesis.

According to the present invention there is provided a prosthesis for insertion into transverse prepared grooves of substantially uniform transverse cross-section along the length thereof in opposed faces of adjoining vertebrae of a vertebral column, adjoining vertebrae having a disc space therebetween, said prosthesis, when inserted, comprising side-by-side rigid inert plugs of generally uniform transverse cross-section along the length thereof, to form transverse struts bottomed on the prepared grooves of adjoining vertebrae and maintaining a desired disc space between said adjoining vertebrae, each plug having an end face with tool receiving means extending internally of the plug for fixedly mounting the plug endwise on a tool to facilitate endwise insertion of the plug on the prepared grooves, a peripheral surface of the plugs being roughened over substantially the whole area thereof for interlocking with said prepared grooves to facilitate bone ingrowth from the vertebrae, each plug having at least one slot therethrough, adapted to receive bone graft material.

The plugs may have many different shapes and peripheral configureations.

The preferred plugs have one end thereof provided with an internally threaded axial hole and can have wings or radial slots radiating from this hole in the end face so that an insertion tool can be threaded into the hole and a sleeve of the insertion tool can be fitted into the slot recess. For example, a cylindrical plug, supported endwise on the tool can be inserted in prepared sites of the adjacent vertebrae and when properly positioned, the sleeve can be held against rotation and the tool unthreaded from the plug without shifting the plug. The radial slot is not needed where the plugs and sites are shaped to prevent rotation.

The sites are preferably formed by a drill surrounded by a drill guard with projecting teeth mbedded in the post rior ends of adjacent v rtebrae to correctly position the drill for forming channels in th opposed faces of adjacent vertebrae. Th channels are sufficiently wide and long to include hard cortex bone but preferably do not extend completely through the anterior side of the vertebrae. Conversely, if the drill is inserted from the anterior site of the vertebrae, the drilling operation is stopped short of the posterior side.

The plugs can be made of an inert rigid metal, such as stainless steel, cobalt-chromium-molybdenum alloys, titanium or the like. The plugs can be provided with roughened surfaces forming pits, prongs, bristles, nubs, or the like irregularities for anchoring bone ingrowth. These roughened surfaces can be part of the plug body or a coating on the body, such as a resin polymer. Bristle or prong surfaces can be rigid or flexible and, if desired, shaped to facilitate insertion and resist retraction.

Preferred roughened surfaces include knurled surfaces, pitted surfaces, barbed surfaces, bristle surfaces and threaded surfaces engaging the prepared sites.

In one preferred embodiment the roughened surfaces are barbs or nubs radiating from the plug periphery or sides. The barbs may be deformable in the direction of insertion of the plug to facilitate insertion on the prepared site. The barbs and nubs can bite into the prepared sites upon attempted retraction of the plug.

The roughened surfaces can be on the periphery of a plastic material coating on the plug.

The plug is preferably composed of a radiolucent material.

The plug preferably has a length greater than its height and a width less than its height.

In one embodiment, the plug has at least one slot therethrough adapted to be packed with bone graft material.

Preferably the slotted plug has a longitudinal vertical slot and a transverse horizontal slot intersecting the vertical slot to receive the bone graft material.

In a preferred embodiment the plug has a myriad of radially extending nubs, the surface thereof separated by grooves. The nubs preferably have included front faces.

In one embodiment the plug has a bevelled front face and a rear face with a tool receiving recess.

A preferred threaded hole in the end face of the plug determines less than one half the length of the plug and has a diameter of less than 1/3 the diameter of the plug. Preferably, a wing or slot radiates diametrically from the hole in the end face of the plug, but terminates inwardly from the periphery of the plug.

A preferred polymer coating to form th roughened surface is nylon, a polyolefin, a vinyl, or the like resin resistant to deterioration in the envi-

ronment of th implant.

The present inv ntion now also provides rectangular vertebral prosthesis implant plugs or blocks fitting rectangular transverse or perpendicular channels or grooves cut in the adjoining faces of vertebral bodies having heights that will stretch the remaining annulus tissue of the discs therebetween still connecting the vertebrae. Flat-sided rectangular or square blocks or plugs are provided to fit these transverse rectangular channels or slots and have bevelled or tapered leading ends easily inserted into the open ends of the transverse slots to spread the vertebrae apart so that the top and bottom faces of each block or plug are tightly bottomed in the slot with the stretched disc tissues causing the vertebrae to grip the plugs. These plugs are inserted laterally or transversely of the vertebral column into the slots while mounted on the end of an insertion tool, have roughened surfaces to facilitate the bone ingrowth and can also have vertical or horizontal slots therethrough or intersecting vertical and horizontal slots, packed with bone graft material, such as stips of bone excised from the iliac crest of the pelvis. This implant material provides a block of living bone that grows all around and through the implant plug into the bone of the vertebrae.

Also, according to this invention, the blocks or plugs instead of being made of an inert metal, can be made of a radiolucent material, such as a plastic of the nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone type, preferably filled with glass or carbon fibres. These plastics can be injection molded, are light in weight, have great load carrying strength and provide improved X-ray visualisation of bone healing. Fiber reinforced plastics composed of such materials filled with glass or carbon fibers are also desirable. A preferred material is a polyether sulfone resin filled with glass and carbon fibers. Suitable carbon fiber composites are supplied under the tradename "VICTREX P.E.S." which is polyether sulfone filled with carbon fibers. Suitable graders are "4101 G.L.-30" which is a 30 percent fiber glass filled and "450 C.A.-30" which is a 30 percent carbon fiber filled. These materials are supplied from ICI Industries of Wilmington, Delaware. Carbon-carbon fiber plastics of the type sold by Fiber-Rite Corporation of Winona, Minnesota, are useful.

The invention will now be further described by way of examples with reference to the accompanying drawings, in which:

Fig.1 is a side elevational view of the lower portion of a human vertebral column with parts broken away and shown in section to illustrat prosthetic implants of this inv ntion insert d between several of the lower vertebra to support the vertebrae in place of th human disc therebetween which has b en partially excised to remove damaged and herniated tissue,

Fig.2 is a posterior elevational view of a portion of Figure 1 taken along the line XIII-XIII of Figure 1.

Fig.3 is a transverse sectional view, with parts in elevation and broken away in section, along the line XIV-XIV of Figure 2.

Fig.4 is an enlarged fragmentary side elevational view, with parts broken away and shown in vertical section, illustrating the manner in which a trial or gauge plug or block of this invention is inserted in position in the transverse rectangular slots of adjoining vertebrae to stretch the remaining interposed disc tissue connected to these vertebrae and to gauge the sites for receiving a proper sized permanent implant.

Fig.5 is a plan view of a vertebrae disc with the interior pulp removed and with disc tissue partially excised to provide gaps or slots aligned with channels cut in the vertebrae to receive the plugs therethrough.

Fig.6 is a perspective view of a smooth faced trial or gauge plug or block for use as shown in Fig.4.

Fig.7 is a perspective view of a preferred form of permanent implant plug or block of this invention.

Fig.8 is a longitudinal vertical sectional view of the plug of Fig.7 taken along the line XIX-XIX of Fig.7.

Many other types of rough or irregular surfaces can be provided on the devices of this invention including porous metal coatings composed of metal balls and beads sintered on a rigid metal substrate as further disclosed in the aforesaid Patent No. 4,743,256.

The prosthetic implants are shown on the drawings as mounted in side-by-side parallel relation forming a pair of struts which maintain the disc space being snugly seated on hard cortex bone to carry the load. These implants have surfaces facilitating rapid bone ingrowth which will fuse the implants to the adjacent vertebrae in a relatively short growth period.

In Figures 1-3, the reference numeral 100 illustrates generally the lower portion of a human vertebral column with adjacent vertebrae supported on prosthetic implant blocks or plugs 111 of this invention.

Fig.4 shows the manner in which adjacent vertebrae are spread apart to stretch collapsed intervening disc tissue as a gauge or trial block of this invention is inserted laterally into transverse rectangular slots of adjoining vertebrae.

In FIGURE 1, th v rtebral column 100 shows the fiv lower vertebrae Nos. 1-5. Adjacent verte-

brae Nos. 2 and 3 and adjacent v rtebrae Nos. 3 and 4 ar separated by and supported on th prosthetic implant blocks or plugs 111 of this invention. Vertebrae Nos. 1 and 2 and vertebrae Nos. 4 and 5 are illustrated as supported on and separated by healthy or undamaged human discs 112 maintaining a normal disc space 113 between the adjoining vertebrae.

Damaged portions of the natural human discs 112 have been excised from the vertebrae Nos. 2 and 3 and Nos. 3 and 4 with the disc spaces 114 being maintained by the implant blocks or plugs 111. It is preferred to retain as much as possible of the healthy annulus tissue of the discs 112 between the vertebrae so that the remaining disc tissue 112a will at least partially surround the implants and will be held under tension by these implants. However, some of the remaining annulus disc tissue may have to be excised to open up spaces for the implant plugs 111.

The opposed faces of adjoining vertebrae have aligned flat-sided rectangular channels or grooves 115 cut therein transversely of the axis of column 100 to first snugly receive test blocks or plugs of this invention for determining the proper sizes for the permanent implants 111. These transverse channels 115 are sufficiently wide and deep to span the central soft cancellous bone and include the hard cortex bone of the adjacent vertebrae. The undamaged human disc tissue 112a remaining between the vertebrae is also cut or trimmed to receive the implants 111 so that as much healthy annulus fibrous tissue as is available will surround the implants.

The preferred flat-sided rectangular channels 115 have blind ends 116 to be abutted by the implants 111.

As shown in FIGURES 2 and 3, the implants 111 are in the form of a pair of side-by-side rectangular plugs inserted endwise into the transverse channels 115. These channels have flat bottoms and sidewalls to snugly embrace the top and bottom ends and side faces of the rectangular plugs. The soft cancellous bone of the vertebrae is illustrated at 117 in FIGURE 3 and is surrounded by the hard cortex bone 118. The channels 115 include portions of this hard cortex bone so that the implants 111 span the softer cancellous bone and rest on the hard cortex bone 118.

The channels 115 can be formed by a mortise cutting chisel tool and in the event disc tissue 112a blocks the paths for the plugs 111, tissue can be trimmed or spread apart to open up the paths.

The implant plugs of blocks 111, as shown in FIGURES 7 and 8, are rigid, inert, solid, flat-sided rectangles, higher than wide and longer than high. They are used in co-operation with trial or gauge blocks, such as 119, shown in FIGURE 6. These blocks 119 have flat, smooth sides and nds with flat top and bottoms 119a, flat sid s 119b, a flat front nd wall 119c, and a flat back end wall 119d. The front wall 119c is bevelled to a reduced rectangular nose surrounded by flat-sided tapered walls 119e with rounded corners 119f.

The back end wall 119d has an internally threaded blind axial hole 119g at the center of the wall.

The gauge blocks 119, in typical surgical operations, will have a length of about 25 mm, a width of about 11 mm and will vary in height from say, 13 to 17 mm, although it should be understood that these parameters may vary greatly and may depend on the size of the spinal column of the recipient. The tapers 119e are preferably about 30 degrees. The rounded corners 119f of the bevels eliminate sharp corners between the top, bottom and sides of the beveled faces.

As shown in FIGURE 4, a trial or gauge block 119 is selected for force-fitting into the channels 115 while mounted on a tool 120 threaded into the hole 119g. The beveled front end 119c of the block will pass through any portion of the disc tissue 112a covering the entrance mouths of the channels 115 by either cutting holes through the remaining tissue or by spreading apart the fibers of the disc to accept the gauge blocks 119.

As shown in FIGURE 5, the remaining healthy disc tissue 112a of a disc 112 between the channel cut vertebrae is trimmed to open up slots 121 permitting access of the gauge blocks 119 to the channels 115. These slots register with the channels 115 and can have open front ends 121a and blind back ends 121b. It is preferred to remove the nucleus pulposus from the damaged disc 112 leaving an annulus of fibrous tissue connecting the adjoining vertebrae and surrounding the inserted blocks.

A proper fitting gauge block 119 is selected by trial and error insertions into the channel cut vertebrae. These blocks are smooth faced and can be removed even when tightly fitted in the channels 115.

As shown in FIGURE 4, a gauge block 119, threaded on the end of on insertion tool 120 is selected to have a height greater than the height between the bottoms of opposed channels 115. Then, when this block is pushed through the open ends of the aligned channels 115, the beveled nose 119c will engage the bottoms of these channels forcing them apart as the block is pushed into the channels thereby stretching any disc tissue 112a still connecting the vertebrae. The block is pushed against the blind ends 116 of the channels and the tension on th disc fibers is determined. Wh n a block 119 of sufficient size to properly load the disc tissue and to fit snugly in the channel, is

located, a permanent implant plug 111 of a siz just slightly great r than the gauge block is selected. Such a permanent plug is then threaded on the end of a tool 120, the gauge block 119 is withdrawn, and the permanent implant 111 on the tool is forced into a position in the channels 115.

A preferred permanent implant block or plug 111 is illustrated in FIGURES 7 and 8. This plug has about the same flat side dimensions as the selected gauge block, but has projected from these flat top, bottom and sidewalls, a pattern of raised annular nubs 122 providing a roughened surface, biting into and gripping the bottoms and sidewalls of the rectangular channels 115. These nubs are separated by annular grooves 123 and longitudinal channels 123a so that each nub 122 will have a flat vertical back wall 122a, a pair of flat vertical sidewalls 122b and an inclined front face 122c.

The plug 111 has the same reduced nose 111a surrounded by the same bevelled sidewalls 111b as the nose 119c and bevelled sidewall 119e of the gauge block 119. In addition a vertical back wall 111c is the same as the back wall 119d and contains the same internally threaded hole 111d as the back wall 119d of the gauge block 119.

Further, the implant plug 111 has a vertical slot 124 therethrough connecting the tops and bottoms of the plug. This vertical slot 124 is rectangular, has a width about 1/3 the width of the block and a length extending close to the front and rear ends of the plug.

This slot 124 is intersected centrally by a horizontal through slot 125. It will be understood that, alternately, the block 111 may have only a single horizontal or vertical slot.

The slots 124 and 125 provide cavities in the block or plug 11 which are filled with strips of bone implant 126 preferably harvested from the pelvis bone of the recipient. This bone material housed in the implant plugs 111 will soon grow out of the grooves or channels 124 and 125 into the radial and longitudinal channels between the nubs 122 surrounding the plugs 111 and will then grow into the bone tissue of the adjoining vertebrae.

The implant plug is easily inserted in the prepared sites 115 from the posterior side of the vertebrae by means of the tool assembly 120 having a threaded end 119c mating with a tapped hole 111d in an end face of the plug 111.

When the implant plug is pushed into its seated position between the vertebrae, the inclined front faces of the nubs 122 will accommodate the forward moving of the plug to the blind ends 116 of the channels 115, but the sharp apexes of the nubs will prevent retraction of the plugs since they will bite into the vertebrae bone. Th r fore, onc th plugs are seated in proper position, they will not shift from this position.

It is preferred that the height of the plugs 111 will be sufficient to maintain a tension load of about 9.1 to 13.6 kg (about 20 to 30 pounds) on the disc tissue. Such a tension load not only pulls the vertebrae tightly against the plugs, but also accelerates bone ingrowth.

The preferred prosthesis plugs or blocks 111 of this invention not only facilitate and simplify the surgical procedure but also accelerate interbody fusion of the vertebrae with the plug. The roughened surfaces provided by the nubs thus serve a multiple purpose of anchoring into the vertebrae, and providing channels for bone ingrowth.

Claims

1. A prosthesis for insertion into transverse prepared grooves of substantially uniform transverse cross-section along the length thereof (115) in opposed faces of adjoining vertebrae (2-3, 3-4) of a vertebral column (100), adjoining vertebrae having a disc space therebetween, said prosthesis, when inserted, comprising side-by-side rigid inert plugs of generally uniform transverse cross-section along the length thereof (111) to form transverse struts bottomed on the prepared grooves of adjoining vertebrae and maintaining a desired disc space between said adjoining vertebrae, each plug having an end face with tool receiving means (111d) extending internally of the plug for fixedly mounting the plug endwise on a tool (120) to facilitate endwise insertion of the plug on the prepared grooves, a peripheral surface (122) of the plugs being roughened over substantially the whole area thereof for interlocking with said prepared grooves to facilitate bone ingrowth from the vertebrae, each plug having at least one slot (124,125) therethrough, adapted to receive bone graft material (126).

2. A prosthesis as claimed in claim 1, wherein the plug roughened surfaces are barbs (122) radiating from each plug and having leading faces (122c) sloping toward the tool receiving end of the plug to bite into the vertebrae and provide extended areas receiving bone ingrowth.

3. A prosthesis as claimed in claim 1 or 2, wherein the tool receiving means is an internally threaded hole (111d) in the end face of each plug for threaded engagement with the end of the tool.

4. A prosthesis as claimed in claim 3, wherein ach plug comprises a radial slot in the end face radiating from the internally threaded hole.

5. A prosthesis as claimed in any on of th preceding claims, wh rein each said plug ccompris s radioluc nt material.

6. A prosthesis as claimed in any one of the preceding claims, wherein each plug comprises a nylon, polycarbonate, polypropylene, polyacetal or polysulfone plastic which is filled with glass or carbon fibres.

Patentansprüche

1. Prothese zum Einsetzen in querliegende vorbereitete Furchen mit im wesentlichen gleichförmig durchverlaufendem Querschnitt über ihre Länge (115) in gegenüberliegenden Flächen benachbarter Wirbel (2-3, 2-4) einer Wirbelsäule, wobei benachbarte Wirbel einen Scheibenabstand zwischen sich haben, wobei die Prothese, wenn sie eingefügt ist, nebeneinanderliegende starre inerte Pfosten mit im wesentlichen gleichförmig durchverlaufendem Querschnitt über ihre Länge (111) aufweisen, um Querstreben zu bilden, die auf den Boden der vorbereiteten Furchen aufgelegt sind und einen gewünschten Scheibenabstand zwischen den benachbarten Wirbeln aufrechterhalten, wobei jeder Pfosten eine Endfläche mit einer werkzeugaufnehmenden Einrichtung (111d) hat, die sich innen in dem Pfosten erstreckt, zum festen Anbringen des Pfostens am Ende auf einem Werkzeug (120) mit den Enden aneinander, um das Einfügen des Pfostens in die vorbereiteten Furchen mit den Enden aneinander zu erleichtern, wobei eine Umfangsfläche (122) der Pfosten über im wesentlichen deren gesamte Fläche zum Zusammenschluß mit den vorbereiteten Furchen aufgerauht ist, um das Einwachsen von Knochen vom Wirbel zu erleichtern, wobei jeder Pfosten wenigstens einen durchgehenden Schlitz (124, 125) hat, ausgelegt zum Aufnehmen von Knochentransplantatmaterial (126).

2. Prothese nach Anspruch 1, bei der die aufgerauhten Oberflächen des Pfostens Widerhaken (122) sind, die von jedem Pfosten strahlenartig ausgehen und Vorderflächen (122c) haben, die sich auf das werkzeugaufnehmende Ende des Pfostens zu abschrägen, um in den Wirbel zu schneiden und ausgedehnte Flächen, die einwachsenden Knochen aufnehmen, zu schaffen.

3. Prothese nach Anspruch 1 oder 2, bei der die werkzeugaufnehmende Einrichtung ein innen mit G winde versehenes Loch (111d) in der Endfläch jedes Pfostens zum Gewindeeingriff mit dem Ende des Werkzeuges ist.

4. Prothese nach Anspruch 3, bei der jeder Pfosten einen radialen Schlitz in der Endfläche aufweist, der von dem innen mit Gewinde versehenen Loch strahlenartig ausgeht.

5. Prothese nach einem der vorangehenden Ansprüche, bei der jeder der Pfosten strahlendurchlässiges Material aufweist.

6. Prothese nach einem der vorangehenden Ansprüche, bei der jeder Pfosten einen Nylon-, Polycarbonat-, Polypropylen-, Polyacetal- oder Polysulfonkunststoff aufweist, der mit Glas- oder Carbonfasern gefüllt ist.

Revendications

1. Prothèse à insérer dans des rainures transversales préparées ayant une section droite transversale sensiblement uniforme sur toute leur longueur (115) taillées dans les faces opposées de vertèbres adjacentes (2-3, 3-4) d'une colonne vertébrale (100), les vertèbres contiguës ayant entre elles un espace discal, ladite prothèse, une fois mise en place, comprenant des fiches inertes rigides placées côte à côte ayant une section droite transversale généralement uniforme sur leur longueur (111) pour former des jambes de force transversales enfoncées sur les rainures préparées des vertèbres voisines et en maintenant un espace discal souhaité entre lesdites vertèbres voisines, chaque fiche ayant une face d'extrémité comportant un moyen de réception d'outil (111d) orienté à l'intérieur de la fiche de manière à monter rigidement la fiche en bout sur un outil (120) afin de faciliter l'insertion en bout de la fiche sur les rainures préparées, une surface périphérique (122) des fiches étant rendue rugueuse sensiblement sur toute sa surface de façon à assurer un verrouillage avec lesdites rainures préparées et à faciliter la croissance de l'os à partir des vertèbres, chaque fiche présentant au moins une fente (124,125) qui la traverse, prévue pour recevoir un greffon osseux (126).

2. Prothèse selon la revendication 1, dans laquelle les surfaces rugueuses de la fiche comprennent des barbelures (122) partant de chaque fiche et ayant des faces avant (122c) en pente vers l'extrémité de réception d'outil de la fiche afin de se fixer dans les vertèbres et de créer des zones étendues dans lesquelles la croissance osseuse peut s'effectuer.

3. Prothès selon la revendication 1 ou 2, dans laquelle l moyen d réception de l'outil est un

orifice filetéintérieurement (111d) formé dans la face d'extrémité de chaque fiche pour permettre une prise par vissage de l'extrémité de l'outil.

4. Prothèse selon la revendication 3, dans laquelle chaque fiche comporte une fente radiale dans la face d'extrémité partant de l'orifice fileté intérieurement.

5. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle chacune desdites fiches est constituée d'un matériau radiotransparent.

6. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle chaque fiche est constituée d'une matière plastique en nylon, polycarbonate, polypropylène, polyacétate ou polysulfone, chargé de fibres de verre ou de fibres carbone.

FIG. 1

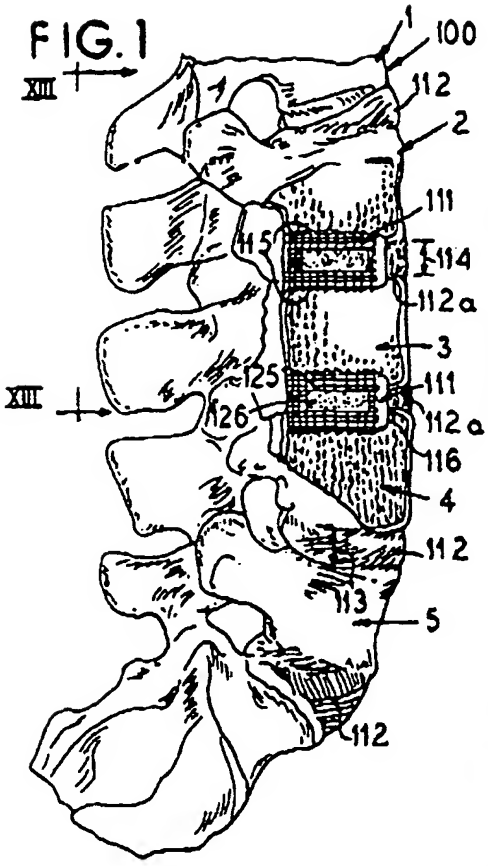

FIG. 2

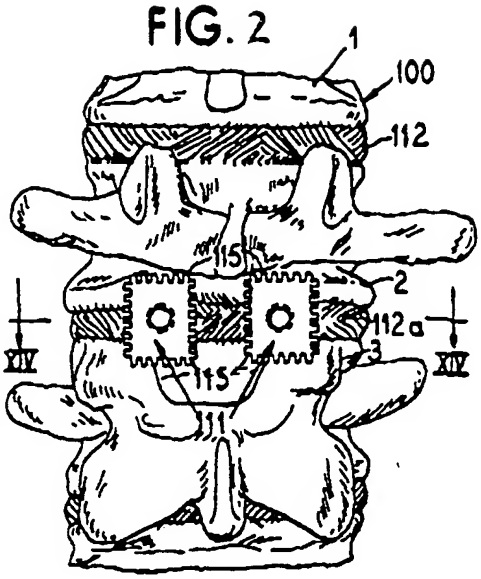

FIG. 3

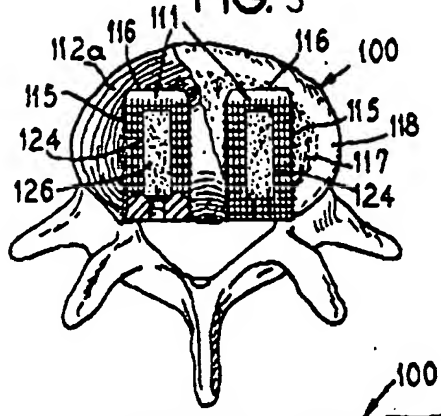

FIG. 4

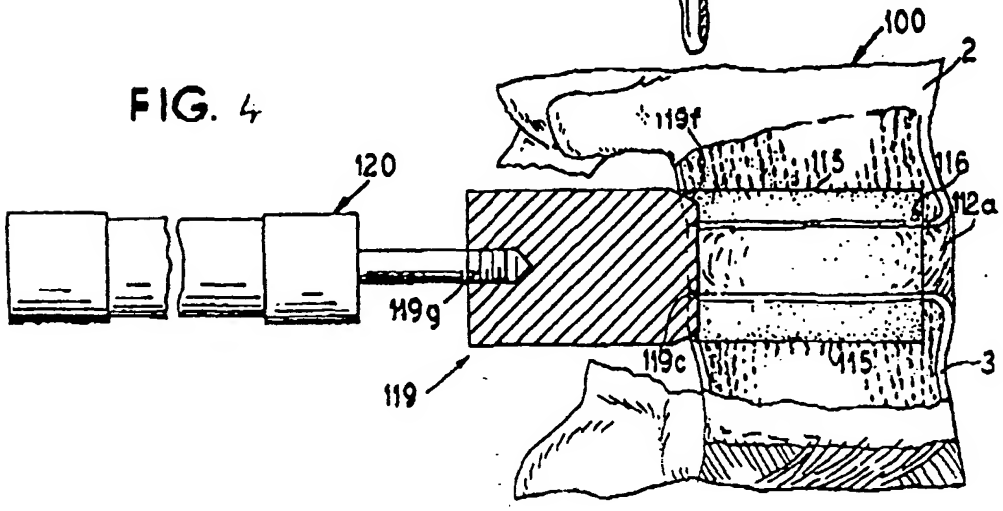

FIG. 5

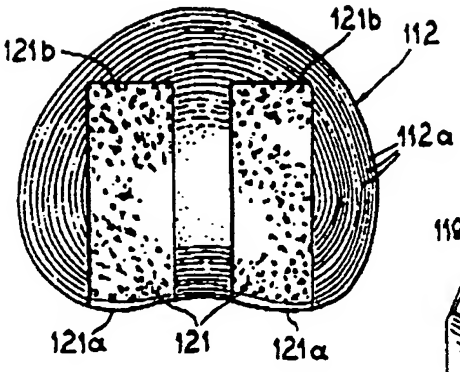

FIG. 6

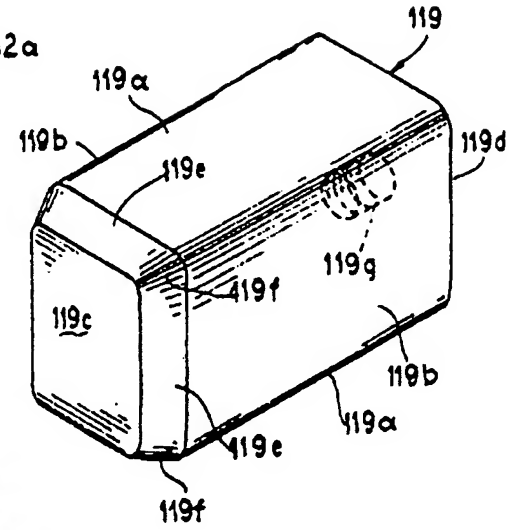

FIG. 7

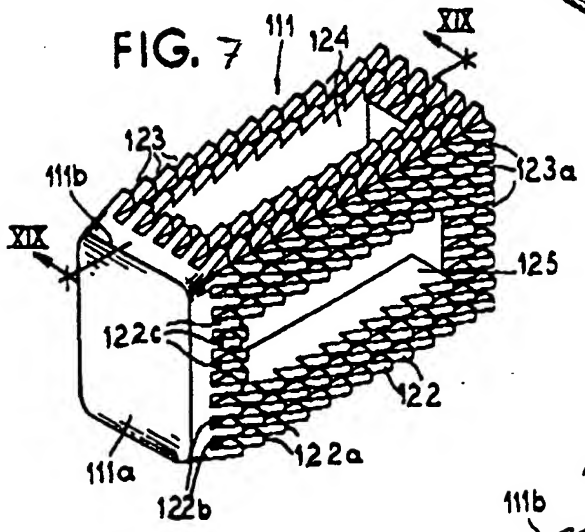

FIG. 8